IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS LLC, PF PRISM C.V., PFIZER PHARMACEUTICALS LLC, and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. 16-1305-RGA
ALEMBIC PHARMACEUTICALS, LTD., ALEMBIC PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	**CONSOLIDATED**
Defendants.	)	

RESPONSE TO PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE CERTAIN EXPERT TESTIMONY BY CRAIG W. LINDSLEY, PH.D.

Dr. Lindsley, an eminently credentialed and experienced individual in the subject matter of the patents at issue in this case, will offer opinions that the asserted claims of the '148 and '625 patents are invalid in view of 35 U.S.C. § 102(a) prior art.[1] In an effort to overcome this prior art, Plaintiffs will argue they were diligent in attempting to reduce the purported inventions of the '148 and '625 patents to practice after an alleged conception date earlier than the filing date of those patents. Dr. Lindsley disagrees Plaintiffs' factual evidence supports their claim of diligence. Plaintiffs want to exclude Dr. Lindsley's testimony relating to their claims of diligence and prevent defendants from putting forth any evidence on this topic. In their motion, Plaintiffs

[1] Dr. Lindsley will also offer opinions that the asserted claims are invalid in view of 35 U.S.C. § 102(b) and 102(e) prior art, and pursuant to 35 U.S.C. § 112. However, Plaintiffs' arguments about conception and diligence, which are at the heart of Plaintiffs' motion, are only relevant to Dr. Lindsley's invalidity opinions involving 35 U.S.C. § 102(a) prior art.

do not argue Dr. Lindsley lacks sufficient experience to offer his testimony, nor do they argue he lacks an appropriate basis for his opinions. Instead, Plaintiffs sole argument is Dr. Lindsley's opinions will not be helpful to the Court. But Dr. Lindsley's opinions as to industry practices and Plaintiffs' efforts in relation to those practices are squarely relevant to, and therefore "fit," the issue of diligence. Plaintiffs' motion therefore should be denied.

I. Factual Background

The '148 and '625 patents claim methods for "treating" or "inhibiting" chronic myelogenous leukemia ("CML") with bosutinib, a tyrosine kinase inhibitor, and claim priority to a provisional application filed on November 6, 2003. Dr. Lindsley will offer opinions demonstrating those patents are invalid as both anticipated and obvious in view of 35 U.S.C. § 102(a) prior art. To get around this invalidating art, Plaintiffs are expected to try to present testimonial and documentary evidence in support of their argument the purported inventions were conceived as early as May 20, 2002 and that they were diligent in reducing them to practice. Dr. Lindsley is expected to testify the evidence Plaintiffs will attempt to present does not support their claims of diligence.

Dr. Lindsley received his Ph.D in Chemistry in 1996 and thereafter worked in the pharmaceutical industry as a medicinal chemist for three different companies over approximately seven years. (D.I. 226, Ex. B at ¶ 6.) In these positions, Dr. Lindsley worked on a number of kinase programs and became "very familiar" with CML and kinase inhibitors, specifically developing a number of products involving both. (*See id.* at ¶¶ 6–7.) Through his work, Dr. Lindsley gained significant experience relating to the conception and reduction to practice of inventions in the general subject area of the patents-in-suit. (*Id.* at ¶¶ 8–9.) Additionally, since his time in industry, Dr. Lindsley has been a professor at Vanderbilt University, where he continues to work in drug development in partnership with pharmaceutical companies and

employs the same industry guidelines regarding conception and reduction to practice he followed in industry, including processes of disclosure, patent applications, and recordkeeping. (*Id.* at ¶ 10.) Accordingly, his areas of expertise include drug discovery and development, particularly relating to kinase inhibitors such as those detailed in the '148 and '625 patents. (*Id.* at ¶ 7.)

Based on his extensive experience in industry and academia, specifically in the fields of drug development, Dr. Lindsley has expressed an opinion that—even if Plaintiffs conceived of the inventions as of the May 20, 2002—they thereafter failed to exercise reasonable diligence in reducing those conceptions to practice. (*Id*. at ¶¶ 75–82.) Plaintiffs have moved to exclude Dr. Lindsley's opinions on this issue by arguing that the opinions "will not 'help the trier of fact to understand the evidence or to determine a fact in issue.'" (D.I. 226 at 4 (quoting Fed. R. Evid. 702(a)).)

II. Legal Standard

"[T]he permissible scope of expert testimony is quite broad, and District Courts are vested with broad discretion in making admissibility determinations." *Hill v. Reederei F. Laeisz G.M.B.H., Rostock*, 435 F.3d 404, 423 (3d Cir. 2006). Admissibility of expert evidence is governed by Federal Rule of Evidence 702, which "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). Plaintiffs here argue only that Dr. Lindsley's testimony fails to meet the third element, that it does not "fit" the issue of diligence.[2] (*See* D.I. 226 at 4.)

[2] Without explaining the relevance to their motion, Plaintiffs argue "Dr. Lindsley sheds no light on what would make him – or anyone for that matter – a 'diligence' expert," and that "Dr. Lindsley acknowledged that he has not studied, taught or published on diligence in relation to practice." (D.I. 226 at 4–5.) Although providing no further argument or authority on these points, they gesture at Dr. Lindsley's *qualifications* as an expert, rather than the fit of his opinions to this case. *See Betterbox Commc'ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 328 (3d Cir. 2002) (noting that qualification as an expert under Rule 702 requires "'specialized knowledge' regarding the area of testimony" which "can be practical experience as well as academic training and

"In assessing whether an expert's proposed testimony 'fits,'" this Court asks "whether [the] expert testimony proffered . . . is sufficiently tied to the facts of the case that it will aid the [trier of fact] in resolving a factual dispute." *United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010) (citations omitted) (first and second alterations in original). "Put another way, this is a question of relevance, and 'Rule 702, which governs the admissibility of expert testimony, has a liberal policy of admissibility' if [the testimony] has the 'potential for assisting the trier of fact.'" *Id.* (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir.1997)) (further citations omitted).

III. Dr. Lindsley's Testimony "Fits" The Issue Of Reasonable Diligence; The Motion Therefore Should Be Denied.

Because Dr. Lindsley's opinions concern industry practices specific to the pharmaceutical industry—and the development of kinase inhibitors and CML products more specifically—and because his opinions relate those practices to the facts of this case, his testimony will be helpful to the Court in determining whether Plaintiffs were diligent in reducing their purported invention(s) to practice. The opinions therefore are admissible under Rule 702 and the motion should be denied.

Defendants will present argument the '148 and '625 patents are anticipated by or obvious in view of 35 U.S.C. § 102(a) prior art.[3] In order to show that the '148 and '625 patents in fact take priority over that prior art, Plaintiffs are expected to argue they conceived of the

---

credentials") (citation and internal quotation marks omitted). However, Plaintiffs fail to put forward any additional argument or any authority at all regarding Dr. Lindsley's qualification as an expert, and have waived this point. *Fed. Election Comm'n v. O'Donnell*, 209 F. Supp. 3d 727, 737 (D. Del. 2016) (holding argument waived under D. Del. L.R. 7.1.3(c)(2) because parties "are not permitted to reserve material for a reply brief that could and should have been included in their opening brief").

[3] Defendants will also argue that the asserted claims are invalid in view of 35 U.S.C. § 102(b) and 102(e) prior art, and pursuant to 35 U.S.C. § 112.

invention(s) as early as May 2002 and then exercised "reasonable diligence toward reduction to practice from a date just prior to" that prior art. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577–78 (Fed. Cir. 1996); 35 U.S.C. § 102(g).[4] Reasonable diligence is a question of law "predicated on subsidiary factual findings." *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 958 (Fed. Cir. 2016) (citation and internal quotation marks omitted). Defendants understand Plaintiffs intend to present documentary and other evidence in addition to testimony in support of their argument that they were reasonably diligent in reducing their conceptions to practice.[5]

In ultimately determining whether Plaintiffs have met the standard, this Court will "view the proffered evidence as it would be viewed by persons experienced in the field of the invention." *Brown v. Barbacid*, 436 F.3d 1376, 1382 (Fed. Cir. 2006). As his report and deposition establish, Dr. Lindsley is a person experienced in the field of the invention and qualified to testify as to the proffered evidence: he has significant experience developing and attempting to patent kinase inhibitors targeted at CML, the precise type of products claimed in the '148 and '625 patents. (D.I. 226, Ex. B at ¶¶ 6–9.) He is familiar with industry practices regarding the development and patenting of similar products from his work with three companies over seven years, as well as his continuing academic career. (*Id.* at ¶¶ 6–11, 13; D.I. 226, Ex. C at 84:24–86:16.) His testimony will therefore assist the Court in determining the diligence of Plaintiffs in reducing their conceptions to practice as viewed by someone experienced in the field: it fits this case and is admissible. *See Golden Bridge Tech., Inc. v. Apple Inc.*, No. CIV. 10-

[4] Although establishing priority in this manner is no longer permissible after the America Invents Act of 2011, the pre-amendment statutes are effective here as the date of each patent predates the effective date of the Act; references to section 102 are therefore to the pre-amendment statute. *See REG Synthetic Fuels, LLC*, 841 F.3d at 958 n.3.

[5] Although Plaintiffs have stated that they will not be presenting expert evidence regarding diligence, (D.I. 226 at 2 n.1), they have provided no authority or argument as to why this would bear on the admissibility of Dr. Lindsley's testimony under Rule 702.

428-SLR, 2013 WL 1431652, at *2 (D. Del. Apr. 9, 2013) (denying *Daubert* motion as to expert's conclusions because "diligence and its corroboration may be shown by a variety of activities") (quoting *Brown*, 436 F.3d at 1380). And while Defendants state—without citation to any authority—that Dr. Lindsley's opinions are inappropriate, courts have routinely considered similar testimony. *E.g.*, *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 106 (D. Del. 2016) (affirming finding of diligence because "[t]he documentary evidence and Mr. Jestice's expert opinions are consistent with Dr. Li's and Dr. Patterson's testimony" on the subject); *Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, 100 F. Supp. 3d 357, 369–70 (D. Del. 2015) (considering competing experts' opinions in deciding reasonable diligence on summary judgment).

The motion should also be denied to the extent it targets Dr. Lindsley's conclusions that Plaintiffs in this case were not reasonably diligent in reducing their conceptions to practice. Without providing specific argument or authority, Plaintiffs imply that Dr. Lindsley's opinion is improper because it addresses "how the Court should decide the issue." (D.I. 226 at 5.) But experts "are not forbidden from offering opinions on technical matters that lead them to particular conclusions that bear on ultimate issues in the case." *Sonos, Inc. v. D & M Holdings Inc.*, 297 F. Supp. 3d 501, 511 (D. Del. 2017); *see also* Fed. R. Evid. 704 ("An opinion is not objectionable just because it embraces an ultimate issue."). And, as Plaintiffs themselves note, they do not challenge Dr. Lindsley's designation as an expert on the technical issues on which his opinions regarding reasonable diligence are based. (*See id.* at 3 n.2.)

Furthermore, crediting Plaintiffs' argument—and concluding that testimony such as Dr. Lindsley's is inappropriate—would leave Defendants effectively unable as a matter of law to present evidence addressing reasonable diligence. As Defendants quite obviously were not privy

to the steps Plaintiffs took in reducing to practice the purported invention(s), the only *possible* evidence they could provide on the issue would be expert testimony of the type that Dr. Lindsley proposes to provide here. Were Plaintiffs' motion to be granted, the Court would decide the issue based exclusively on Plaintiffs' side of the story which Defendants could challenge only through cross-examination but which they could not rebut with their own case. This would be patently unfair. *Cf. Brown v. Barbacid*, 276 F.3d 1327, 1333 (Fed. Cir. 2002) (noting that, in interference proceeding before the Patent Board, "both parties must be given an opportunity to submit evidence regarding priority").

IV. Conclusion

Dr. Lindsley's testimony will help the trier of fact determine whether Plaintiffs were diligent in reducing the purported invention(s) claimed in the '148 and '625 patents to practice. Accordingly, it is admissible under Federal Rule of Evidence 702, and this Court should deny Plaintiffs' motion.

/s/ Nathan R. Hoeschen

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
Attorneys for Defendants Sun Pharmaceutical Industries Inc. and Sun Pharmaceutical Industries Limited

OF COUNSEL:
Stephen P. Benson
Kimberly A. Beis
FREEBORN & PETERS LLP
311 South Wacker Drive, Suite 3000
Chicago, IL 60606
(312) 360-6000

Huiya Wu
Daniel P. Margolis
Cindy Chang
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Joshua Weinger
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-8361

/s/ Kelly E. Farnan

Kelly E. Farnan (No. 4395)
Nicole K. Pedi (No. 6236)
RICHARDS LAYTON & FINGER, PA
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
pedi@rlf.com
Attorneys for Defendants Alembic Pharmaceuticals, Ltd., and Alembic Pharmaceuticals, Inc.

OF COUNSEL:
Bradley C. Graveline
SHEPPARD MULLIN RICHTER & HAMPTON LLP
70 West Madison Street, 48th Floor
Chicago, IL 60602-4492

Jesse A. Salen
SHEPPARD MULLIN RICHTER & HAMPTON LLP
12275 El Camino Real, Suite 200
San Diego, CA 92130-2006

Dated: September 6, 2019